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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,264	12/05/2001	Michael A. Siani-Rose	3407.2	1024
33494	7590	07/26/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER 8TH FLOOR SAN FRANCISCO, CA 94111-3834			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,264

Applicant(s)

SIANI-ROSE ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 20-30, 39-49 and 58-81 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 20-30 and 39-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11, 20-30, 39-49, and 58-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2004 and 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments and amendments, filed 03 May 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

This application contains claims 1-11, 20-30, and 39-49 drawn to non-elected inventions without traverse in the reply filed on 21 November 2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Claims herein under examination are claims 58-81. Claims 12-19, 31-38, and 50-57 have been cancelled.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

NON-STATUTORY SUBJECT MATTER

Claims 74-81 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a "computer-readable medium including instructions for gene characterization" (i.e. computer code).

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M.P.E.P. section 2106 1(a) states:

Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical **>**things.” They are neither computer components nor statutory processes, as they are “acts” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed **>**elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program **>** is a computer element which defines structural and functional interrelationships between the computer program and the **>**rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions.

However, the computer-readable medium of claims 74-81 fails to provide a functional relationship between the computer instructions on the computer-readable medium and computer. The computer-readable storage medium does not cause a computer to execute a specific process; absent is any executable code that would cause a computer to execute a specific process. Therefore, the claims do not recite statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 58-81 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 58-81 are considered new matter. Applicants' indicate in the response filed 03 May 2004 "New claims 58-81 were added to more distinctly claim the invention. Support for the new claims can be found in the specification. No new matter has been added." However, this is not agreed with. There does not appear to be support for such broadly encompassing limitations (i.e. claim 58) throughout the specification or to any of the previously examined claims (claims 12-19, 31-38, and 50-57) which have now been cancelled. For example, new claim 58 and cancelled claim 12 appear at first glance to correspond to one another. However, cancelled claim 12 previously read as follows:

A computer implemented method for gene characterization comprising:
generating libraries of models using structural relationships of known proteins;
inputting a plurality of protein sequences;
comparing the plurality of protein sequences with the models;
automatically establishing criteria for assigning the sequences for each model; and
assigning the sequences to the models based upon the criteria.

whereas new claim 58 reads as follows:

A computer implemented method for gene characterization, the computer-implemented method comprising:
generating a plurality of libraries associated with a plurality of models related to a plurality of structural relationships of known proteins;
receiving a plurality of protein sequences;
processing information associated with the plurality of protein sequences and the plurality of models;
assigning the plurality of protein sequences to the plurality of models based on at least information associated with the plurality of protein sequences and the plurality of models.

As demonstrated (refer to underlining) above particular limitations have been omitted and added, however, without proper support for such omission or addition (i.e. page and line number). Further, the terms "associated" and "related" are found throughout the new claims and it is unclear by way of the specification what Applicants intend such language to embrace (Refer to below 35 U.S.C. § 112 2nd Paragraph). Therefore, new claims 58-81 are considered NEW MATTER.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 58, 66, 74, and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preambles state “A computer implemented method for gene characterization”/“A system for gene annotation”/“A computer-readable medium including instructions for gene characterization”, however the claims recite a final step of “assigning the plurality of protein sequences to the plurality of models based on at least information associated with the plurality of protein sequences and the plurality of models”. There is no indication that a gene is characterized as recited in the preamble nor does the preamble indicate the method is for the assignment of protein sequences to models. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when a gene is characterized. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 58, 59, 63-66, 71-75, 79-81, and all claims dependent therefrom recite the language “associated” which is vague and indefinite. For example, it is unclear the criteria(s)

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that establishes an association between “a plurality of libraries” and “a plurality of models” (claim 58). Applicants can resolve this issue by particularly pointing out the criteria that formulates said association and the associations for claims 59, 63-66, 71-75, and 79-81. Clarification of the metes and bounds, via clearer claim language is requested.

Claims 58, 64, 65, 72, 73, 80, 81, and all claims dependent therefrom recite the term “related” which is vague and indefinite. For example, it is unclear the criteria(s) that establishes a relationship among “a plurality of models” and “a plurality of structural relationships of known proteins”. Applicants can resolve this issue by particularly pointing out the criteria that formulates said relationship and the relationships for claims 64, 65, 72, 73, 80, and 81. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-62, 66-70, and 74-78 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eddy.

Eddy reviews recent literature on methods and software (i.e. computer system with processor & memory and computer program medium) on profile hidden Markov model (profile HMM), wherein said profiles allows for multiple sequence alignment into position-specific scoring system suitable for searching databases for remotely homologous sequences (Abstract; and page 755, right column, lines 18-19). The author discusses three principal advances: 1)

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motif-based HMMs; 2) availability of large libraries of HMMs and multiple alignments; and 3) increase profile HMM methods into the area of protein prediction (page 755, right column, lines 21-30). Eddy discusses profile HMM libraries and their application for modeling a particular sequence family of interest and finding remote homologues in a sequence database (claims 58, 59, 66, 67, 74, and 75; page 759, right column, lines 44-46). The author describes the generation of a library of profile HMMs then querying a sequence (i.e. protein) against said generated library, thereby determining homologues/motif patterns (pages 759-760, beginning on the right column, line 46). Further, it is indicated current releases of databases contain profile for 290 to 1313 protein domains (claims 60-62, 68-70, and 76-78; page 760, left column, lines 20-22). Thus, Eddy anticipates the instantly claimed invention.

No Claims Are Allowed.

ACTION IS FINAL AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

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the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Date:

July 22, 2004

Examiner Initials:

CSM

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER

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